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10/560,457	04/19/2006	Brian Bennett	KILBURN 1180	3027

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EXAMINER	
CHEN, CATHERYNE	

ART UNIT	PAPER NUMBER
1655	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/560,457	BENNETT, BRIAN	
	Examiner	Art Unit	
	Catheryne Chen	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 May 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4 and 7-22* is/are pending in the application.

4a) Of the above claim(s) *18-22* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4 and 7-17* is/are rejected.

7)☒ Claim(s) *9* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *13 December 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Currently, Claims 1-4, 7-22 are pending. Claims 1-4, 7-17 are examined on the merits.

Election/Restrictions

Applicant's election of Group I (Claims 1-4, 7-17) in the reply filed on May 29, 2007 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Specification

The use of the trademarks Nipastat (Trade Mark)), parabens, phenoxyethanol, a isothiazolinone, especially Phenouip (Trade Name), Nipas01 15(Trade Name), Nipagin (Trade Name), Euxyl K100 (Trade Name) page 10 have been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Claim Objections

Claim 9 is objected to because of the following informalities: The claim needs to be a sentence. The claim has no punctuation at the end of the claim. Furthermore, Nipastat is a trademark. The ingredients claimed need to be listed. Appropriate correction is required.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

The claimed invention is directed to non-statutory subject matter.

Claims 12-17 provide for the use of a formulation, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 12-17 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 9, 12-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 9 is indefinite because it does not state that

triclosan and alexidine are included as the active ingredients, while these compounds are required ingredients in the parent claim.

Claims 12-17 are indefinite because it is not clear if applicant is claiming a method or a composition. For the sake of examination, these claims will be considered as composition claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-4, 7-8, 10-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gaffar et al. (US 5368844).

Gaffar et al. teaches oral composition on dental surfaces (column 1, lines 24-25) with triclosan (column 2, line 34), comprising a liquid vehicle suitable for topically contact dental surfaces and gums (column 2, lines 51-55), antibacterial agent amount about 0.01 to 5% by weight (column 4, lines 33-35), alexidine (column 5, lines 9-10) at

bout 0.001 to 15% by weight (column 5, lines 29-30), incorporate preservatives, silicones, flavoring materials (column 13, lines 39-41, 51). However it does not teach the viscosity and claimed concentrations.

Silicone fluid is intrinsically less than 20 Pascal second. Therefore, the oral composition as taught by the reference as a mouthwash or liquid dentrifrice, which is substantially liquid in character (column 12, lines 28-30), is intrinsically less than 20 Pascal second.

The reference also does not specifically teach adding the ingredients in the amounts claimed by applicant. The amount of a specific ingredient in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). Thus, optimization of general conditions is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient to add in order to best achieve the desired results. Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization of ingredient amount would have been obvious at the time of applicant's invention.

Claims 1-4, 7-8, 10-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Littlewood et al. (US 2002/0034478 A1).

Littlewood et al. teaches an oral non-food composition with Triclosan, peppermint extract (paragraph 0002), silicone compound (paragraph 0005), liquid silicone (paragraph 0007), dimethyl polysiloxane with viscosity range of 0.4 to $100X10^{-3}m^2s^{-1}$ at 25 degree Celsius (paragraph 0010), dimethyl siloxane having viscosity of 0.05 to $5X100X10^{-3}m^2s^{-1}$ (paragraph 0012), alexidine (paragraph 0033), preservatives (paragraph 0044), pharmaceutically acceptable carriers (paragraph 0049), surfactants (paragraph 0050), humectants (paragraph 0052), binder and thickeners (paragraph 0053), 0.001 to 10% by weight of silicone (claim 5). However, it does not teach the concentrations.

The reference also does not specifically teach adding the ingredients in the amounts claimed by applicant. The amount of a specific ingredient in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). Thus, optimization of general conditions is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient to add in order to best achieve the desired results. Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization of ingredient amount would have been obvious at the time of applicant's invention.

Claims 1-4, 7-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Littlewood et al. (US 2002/0034478 A1) as applied to claims 1-4, 7-8, 10-17 above, and further in view of Schulze zur Wiesche et al. (WO/2001/085106 with US 2003/0206933 A1 as translation) and Hansen et al. (US 5955502).

Littlewood et al. teaches an oral non-food composition with Triclosan, peppermint extract (paragraph 0002), silicone compound (paragraph 0005), liquid silicone (paragraph 0007), dimethyl polysiloxane with viscosity range of 0.4 to $100X10^{-3}m^2s^{-1}$ at 25 degree Celsius (paragraph 0010), dimethyl siloxane having viscosity of 0.05 to $5X100X10^{-3}m^2s^{-1}$ (paragraph 0012), alexidine (paragraph 0033), preservatives (paragraph 0044), pharmaceutically acceptable carriers (paragraph 0049), surfactants (paragraph 0050), humectants (paragraph 0052), binder and thickeners (paragraph 0053), 0.001 to 10% by weight of silicone (claim 5). However, it does not teach the concentrations and other ingredients.

Schulze zur Wiesche et al. teaches agent for skin (paragraph 0003), in liquid form in aqueous dispersion (paragraph 0203), jojoba oil (paragraph 0208), liquid paraffin oils (paragraph 0209), stearic acid (paragraph 0210), aloe vera (paragraph 0234), silicones (paragraph 0251), Carbomer (paragraph 0321), NIPA (paragraph 0356).

Hansen et al. teaches agent for skin or mucosa (column 1, lines 9-11) with 1,2-propanediol (column 5, line 8), glyceryl monostearate, water (column 6, lines 20-21, 45), triethanolamine (column 15, line 13), castor oil (column 15, line 20), cetyl palmitate (column 15, lines 31-32).

The references also do not specifically teach formulating the composition in the forms claimed by applicant. These pharmaceutical forms are well known in the art to be fatty substances that can be used to make aqueous dispersions due to their bioadhesive properties to make paste or gel formulations (Schulze zur Wiesche et al. paragraph 0203; Hansen et al. column 4, line 44; Littlewood et al. paragraph 0057). Based on this knowledge, a person of ordinary skill in the art would have had a reasonable expectation that formulating the composition taught by the references in the claimed forms would be successful. Therefore, an artisan of ordinary skill would have been motivated to formulating the composition taught by the reference in the forms claimed by applicant.

The references also do not specifically teach adding the ingredients in the amounts claimed by applicant. The amount of a specific ingredient in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). Thus, optimization of general conditions is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient to add in order to best achieve the desired results. Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization of ingredient amount would have been obvious at the time of applicant's invention.

Conclusion

No claim is allowed.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Catheryne Chen whose telephone number is 571-272-9947. The examiner can normally be reached on Monday to Friday, 9-5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Catheryne Chen
Patent Examiner

Art Unit 1655

/Susan Hoffman/
Primary Examiner, Art Unit 1655